

IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF TEXAS  
FORT WORTH DIVISION

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PUBLIC HEALTH AND MEDICAL  
PROFESSIONALS FOR TRANSPARENCY,  
ET AL.,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG  
ADMINISTRATION,

Defendant.

Civil Action No. 4:22-CV-0915-P

**JOINT NOTICE OF CLARIFICATION**

The parties submit this notice to clarify the parties' production agreement, as described in the May 14, 2025 Joint Status Report (ECF No. 49 at ¶ 5a-e). In that Joint Status Report, the parties explained the current status of Defendant's production of two separate files:

(1) the responsive Pfizer COVID-19 supplemental emergency use authorization file for the 12-to-15 years of age indication ("Pfizer sEUA file"), which Defendant had agreed to produce by September 2, 2025 by producing at least 180,000 pages a month with the first production occurring on or before August 1, 2025, and

(2) the responsive Moderna COVID-19 emergency use authorization file ("Moderna EUA file"), which Defendant had agreed to produce by October 1, 2026 by producing at least 180,000 pages a month beginning on or before October 1, 2025.

*See* ECF No. 49 at ¶ 5a-b.

On May 15, 2025, the Court issued an order "based upon the Parties' agreement." ECF No. 50. The Court's Order largely aligned with the parties' production agreement in setting out a production schedule of 180,000 pages a month beginning on October 1, 2025 (i.e., as relevant to

the Moderna EUA file), but the Order did not specifically mention Defendant’s production of the Pfizer sEUA file (which Defendant had agreed to complete by September 2, 2025, with the first production occurring no later than August 1, 2025, *see* ECF No. 49 at ¶ 5a). For the avoidance of doubt, this notice is being filed to confirm that Defendant intends to abide by the complete terms of its agreement with Plaintiffs, including this provision regarding the Pfizer sEUA file.<sup>1</sup> The parties therefore respectfully request that the Court enter an amended version of its May 15, 2025 Order, so as to cover the Pfizer sEUA file as well as the Moderna EUA file. The parties are submitting a proposed order to the Court’s “orders” email address.

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<sup>1</sup> The parties’ agreement does not apply to any other case, including *Public Health and Medical Professionals for Transparency v. FDA*, Civ. A. No. 21-1058 (N.D. Tex.) (“PHMPT I”), where this Court ordered FDA to produce the “responsive EUA file” for the Pfizer COVID-19 vaccine for individuals sixteen years of age and older on or before June 30, 2025. *See* December 6, 2024, Mem. Op. & Order (ECF No. 101).

Respectfully submitted,

/s/ Elizabeth A. Brehm

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Certificate of Service

On June 4, 2025 I electronically submitted the foregoing document with the clerk of court for the U.S. District Court, Northern District of Texas, using the electronic case filing system of the court. I hereby certify that I have served all parties electronically or by another manner authorized by Federal Rule of Civil Procedure 5(b)(2).

/s/ Brian W. Stoltz  
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